DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

MAR 2 3 2001

Our STN: BL 103764/5003

Ann Shea
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Shea:

Your request to supplement your biologics license application for Basiliximab to include use in renal transplantation in combination with triple immunosuppressive therapy; use in pediatric renal transplantation; and use of an IV bolus injection has been approved.

We acknowledge your written commitments to conduct a post marketing study and to provide additional information as described in your letters of March 20, 2001, and March 22, 2001, respectively, as outlined below:

1. To conduct an *in vitro* study to evaluate the functional modulation by Basiliximab of T cells from pediatric, adolescent, adult, and elderly healthy volunteers. The final protocol for this study will be submitted to CBER by September 30, 2001. Patient accrual will begin by January 31, 2002, with projected study completion by May 31, 2002, and final study report submission to CBER by August 31, 2002.

2. To submit to CBER a CBE supplement to increase the prominence of the text describing the content of the vial ["20 mg (single use vial)"] on the carton and vial label by June 30, 2001.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 or Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567 or Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss, M.D.
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research